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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/509,196  | 03/23/2000  | ROGER JOHN DALY      | 1871-129            | 8868             |
| 24353   | 7590        | 02/01/2006           | EXAMINER            |                  |
| BOZICEVIC, FIELD & FRANCIS LLP<br>1900 UNIVERSITY AVENUE<br>SUITE 200<br>EAST PALO ALTO, CA 94303 |             |                      | CHERNYSHEV, OLGA N  |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1649                |                  |
| DATE MAILED: 02/01/2006   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                       |                                    |  |
|------------------------------|---------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/509,196  | <b>Applicant(s)</b><br>DALY ET AL. |  |
|                              | <b>Examiner</b><br>Olga N. Chernyshev | <b>Art Unit</b><br>1649            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-7, 19-22, 24-29 and 31-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7, 19-22, 24-29 and 31-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to remarks***

1. Claims 5-7, 19-22, 24-29 and 31-41 are under examination in the instant office action.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on December 15, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 101***

5. Claims 5-7, 19-22, 24-29 and 31-41 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility essentially for reasons of record in appropriate sections of previous office actions of record.

Applicant initially traverses the rejection on the premises that it is in conflict with the flowchart on page 9 of the Utility Guidelines Training Materials (pages 5 and 6 of the Response). Applicant further submits that "the Utility Guidelines do not require factual evidence within Applicant's disclosure at the time of filing" (middle at page 6) and refers to *In re Hogan and Banks* to support argument that Applicant's asserted utility could be substantiated by post-filing date publications (bottom at page 6). Finally, Applicant argues that article by Daly et al. is "more relevant to breast and prostate cancer than in general Baguley et al. paper [cited by the

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Examiner]. Therefore, at best there is a 50-50 tie, Applicant's word against the Examiner's, and a tie is broken in favor of Applicant" (middle at page 7 of the Response). Applicant's arguments have been fully considered but are not persuasive for the following reasons.

With respect to Applicant's request for clarification regarding the basis of the instant utility rejection and proper use of a flowchart provided with the training materials, Applicant's attention is directed to MPEP 2107. II, section B, which states:

"(B) Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible" (emphasis added). Thus, for purpose of clarification, Applicant's asserted utility must be specific and substantial credible to meet the requirements of 35 USC §101. Further, MPEP 2107. II, section B also states that

"(ii) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions".

Thus, contrary to Applicant's statement, MPEP specifically recites a requirement to present disclosure or evidence of record to support an asserted utility. Because in the instant case the instant specification fails to present any evidence or sound scientific reasoning that the instant claimed polynucleotides could be used as cancer biomarkers, the instant claimed invention clearly lacks utility in currently available form and therefore, does not meet the requirement of 35 USC §101. There appears to be no conflict with the Utility Review flowchart, as lack of specific and substantial credible utility leads to rejection under §101 and §112.

Applicant's arguments regarding relevance of publications of Daly et al., Kishi et al. and Tanaka et. al were considered and fully answered in the previous office action of record. The Examiner maintains the position that the asserted utility of the claimed polynucleotides as cancer biomarkers is not supported by any evidence of record in the instant specification as originally filed and is not substantiated by "other art-related facts existing on the filing date" (bottom at page 6 of the Response).

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. *See In re Fisher*, 2005 WL 2139421 (Sept. 7, 2005). The *Fisher* court interpreted *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility" 2005 WL 2139421, at \*4. The *Fisher* court held that § 101 requires a utility that is both substantial and specific. *Id.* At \*5. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Id.*

The court held that a specific utility is "a use which is not so vague as to be meaningless." *Id.* In other words, "in addition to providing a 'substantial' utility, an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.*

The *Fisher* court held that none of the uses asserted by the applicant in that case was either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for

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that matter, could possible achieve, but none for which they have been used in the real world.”

*Id.* at \*7. Therefore, they are not substantial utilities.

Just as in *Fisher* case where the Board reasoned that use of the claimed ESTs for the identification of polymorphisms is not a specific and substantial utility because “[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage,” (*Id.*, slip op. at 15), in the instant case detection of an isolated polynucleotide molecule of SEQ ID NO: 1 or the encoded polypeptide of SEQ ID NO: 2 provides no information regarding presence or absence of any pathological condition, including breast or other form of cancer.

Thus, for reasons set forth and also reasons of record in the previous communications of record, the claimed polynucleotides do not have a real-world use and do not meet the utility requirements under 35 U.S.C. 101.

### ***Claim Rejections - 35 USC § 112***

6. Claims 5-7, 19-22, 24-29 and 31-41 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Conclusion***

7. No claim is allowed.

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

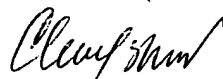
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

January 30, 2006